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Collaborative randomised controlled trial of trigger versus conventional ventilation in preterm infants with respiratory distress syndrome

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
09/10/2014

Condition category
Neonatal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
C/6/16-04-94/BAUMER/F

Study information

Scientific Title

Study objectives
Objectives: To investigate the effects of Patient Triggered Ventilation (PTV) compared with conventional ventilation (Intermittent Mandatory Ventilation [IMV]) in preterm infants ventilated for Respiratory Distress Syndrome (RDS).

Setting: Twenty-two neonatal intensive care units.

Design: Subjects were 924 babies under 32 weeks gestation and within 72 hours of birth ventilated for RDS for less than 6 hours. Telephone randomisation to receive either PTV or IMV. Analysis on "intention to treat" basis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Neonatal diseases

Interventions
1. Trigger ventilation
2. Conventional ventilation

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Death before discharge home or oxygen therapy at 36 weeks gestation
2. Pneumothorax whilst ventilated
3. Cerebral ultrasound abnormality nearest 6 weeks
4. Duration of ventilation in survivors

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/03/1998

Eligibility

Key inclusion criteria
Infants of less than 32 weeks gestation, they are ventilated within 72 hours of birth, and have features compatible with respiratory distress syndrome

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
Babies with evidence of major congenital malformation or evidence of inhalational pneumonitis will be excluded

Date of first enrolment
01/11/1994

Date of final enrolment
31/03/1998

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Plymouth Hospitals NHS Trust
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Executive South West (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2000		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes